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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/885,568	06/20/2001	John Jianhua Chen	S63.2-9515	8081

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EXAMINER

HON, SOW FUN

ART UNIT PAPER NUMBER

1772

DATE MAILED: 10/06/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/885,568

Applicant(s)

CHEN ET AL.

Examiner

Sow-Fun Hon

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-23 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-23 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. ____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). ____.
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 2,4. 6) ☐ Other: .

DETAILED ACTION

Double Patenting

1. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

2. Claims 1-6, 9-10 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-7, 14, 24-36 of copending Application No. 09/696378. Although the conflicting claims are not identical, they are not patentably distinct from each other because both sets of claims overlap in reciting a balloon comprising a polymer matrix and a fiber component wherein the fibers are distributed in a direction relative to the balloon axis, and wherein the fibers comprise liquid crystal polymer material (LCP).

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

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A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claim 14 is rejected under 35 U.S.C. 102(b) as being anticipated by Bland et al. (US 5,427,842).

Bland et al. has a balloon for a medical device (angioplasty) which must inflate to a controlled size and should not stretch to a larger size, but cannot readily tear. It is formed from tear resistant multilayer film comprising alternating layers of relatively stiff and ductile polymeric materials (column 1, lines 10-50). The tear resistant film comprises more than 5 layers and therefore overlaps the claimed range of at least 7 up to 50 laminate layers (column 3, lines 30-50).

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. Claims 1-6, 9-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Boretos (US 4,254,774) in view of Zdrahala (US 5,156,785).

Boretos teaches a balloon catheter which has a one-piece unitary construction which minimizes the possibility of detachment or separation of portions thereof accidentally in a critical area of the body where harm may be incurred to the patient, such as in the area of the brain or lungs (column 2, lines 60-70). To form the balloon, the catheter tubing is heated locally in the

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area where the balloon is desired and then inflated (column 5, lines 40-70). Boretos teaches that the catheter tubing may comprise any suitable thermoplastic material such as polyurethanes and copolyester polymers (column 4, lines 35-45).

Boretos fails to teach the plurality of fibers being distributed in a selected direction relative to the balloon axis and composed of material which has greater tensile strength than the matrix material.

Zdrahala has an extruded catheter tubing which exhibits stiffness in the longitudinal direction as well as rotational stiffness and both may be varied along the length of the tubing (column 1, lines 55-70 and column 2, lines 1-5). The composition contains from 5 to 35 weight percent of the liquid crystal polymer, and the matrix of the blend may be composed of polyurethanes, polyesters and copolyester elastomers which are softer materials than the liquid crystal polymer (column 4, lines 15-35) so that they are either compliant or semi-compliant. The liquid crystal fibers are distributed in the matrix material helically relative to the balloon axis (separate phase of liquid crystal plastic forms helical extending, separate fibrils within the extruded tubing with the fibers (fibrils) being dispersed in the structural plastic matrix) (column 5, lines 1-15). The fibers are thus cores of polymeric material coextruded with the matrix material (column 6, lines 35-22). Since the liquid crystal polymers are rather stiff in the solid state (column 3, lines 35-45) thus having higher tensile strength, the bulk elongation of the liquid crystal polymeric cores is less than 150 % and is less than the softer elastomeric matrix when oriented in the direction of the longitudinal axis.

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The extruded liquid crystal polymer-containing material is coated with a layer of non-liquid crystal polymer material such as softer polyurethanes on both sides (an exterior coating and additionally a coating of the inner lumen as well (column 4, lines 30-50).

The catheter tubing can have a body portion wherein the fibers are oriented substantially parallel to the longitudinal axis of the balloon (orientation to be substantially longitudinal to provide a section of relatively low rotational stiffness and relatively high longitudinal stiffness) (column 2, lines 40-60).

Since Zdrhala teaches that the fibers (fibrils) exhibit an aspect ratio of about 10 to 300, the aspect ratio being defined by the length of the fiber divided by its diameter, in the absence of a showing of unexpected results, it is the examiner's position that the claimed range of the LCP (liquid crystal polymer) fiber diameter of from 0.01 to about 10 microns is a result of routine experimentation.

Since Zdrahala teaches that the fiber reinforced catheter tubing has stiffness in the longitudinal direction as well as rotational stiffness and that both may be varied along the length of the tubing, it would have been obvious to one of ordinary skill in the art to have used the fiber reinforcement taught by Zdrahala in the invention of Boretos in order to obtain a balloon catheter with the desired variance in axial and rotational stiffness along its length.

7. Claims 7-8, 15-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Boretos in view of Zdrahala as applied to claims 1-6, 9-13 above, and further in view of Bland et al. (US 5,427,842).

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Boretos has been discussed above and teaches the balloon catheter tubing for a medical device but fails to teach laminate layers comprising alternating series of fiber-containing and fiber-free layers.

Zdrahala has been discussed above and teaches the catheter tubing for a medical device wherein the catheter tubing contains from 5 to 35 weight percent of the liquid crystal polymer (column 5, lines 16-30). The matrix may be composed of polyurethanes and thermoplastic elastomers such as polyester-polyether block copolymers (HYTREL) and polyamide-polyester (PEBAX) block copolymers (column 4, lines 15-30) which are either compliant or semi-compliant. The layer of liquid crystal polymer fiber blend is laminated on each side with softer polyurethane (column 4, lines 30-50).

Although Zdrahala fails to teach the ratio of the total thickness of the two types of layers, in the absence of a showing of unexpected results, it is the examiner's position that the claimed range of from about 5 to about 15, for the ratio of liquid crystal polymer fiber blend layer to polymer layer, is the result of routine experimentation.

While teaching a laminate of stiff liquid crystal fiber-containing and fiber-free layers, Zdrahala fails to teach the alternating series of fiber-containing and fiber-free layers.

Bland et al. teaches a balloon catheter (angioplasty) for a medical device with the balloon comprising tear resistant multilayer film comprising alternating layers of relatively stiff and ductile polymeric materials (column 1, lines 10-50). The tear resistant film comprises more than 5 layers and therefore overlaps the claimed range of at least 7 up to 50 laminate layers (column 3, lines 30-50).

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Since Bland et al. teaches that the balloon portion of the balloon catheter requires tear resistant multilayer film comprising alternating layers of relatively stiff and ductile polymeric materials, it would have been obvious to one of ordinary skill in the art to have used a laminate of alternating layers of relatively stiff and ductile polymeric materials to form the balloon catheter tubing in the invention of Boretos in order to obtain a balloon catheter with a tear-resistance balloon portion.


It thus follows that it would have been obvious to one of ordinary skill in the art to have alternated the layers of liquid crystal polymer fiber and fiber-free material in the catheter tubing of Zdrahala for use in the invention of Boretos in order to obtain a balloon catheter with a balloon portion having the desired tear resistance as well as the desired rotational and longitudinal stiffnesses at different body portions.

Any inquiry concerning this communication should be directed to Sow-Fun Hon whose telephone number is (703)308-3265. The examiner can normally be reached Monday to Friday from 9:00 AM to 6:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Harold Pyon, can be reached on (703)308-4251. The fax phone number for the organization where this application or proceeding is assigned is (703)872-9310.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703)308-0661.

SH
Sow-Fun Hon
09/24/03


HAROLD PYON
SUPERVISORY PATENT EXAMINER
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